IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF ALFRED INTOCCIA, JR. TAKEN JULY 31, 2013

BSC Designations	Objection	Plaintiffs Counter Designation
ai073113, (Pages 327:17 to 336:17) 328 23 Q For the Boston Scientific slings and POP kits, 24 does Boston Scientific make -- do biocompatibility 329 1 testing to determine whether or not the mesh and the 2 product is biocompatible? 3 A Yes. There's an entire organization department 4 within Boston Scientific that does biocompatibility 5 work. There's standardized tests that are used to 6 determine biocompatibility for all materials. 7 That biocompatibility group has the expertise, 8 the knowledge, the capability of running batteries of 9 tests that determine the biocompatibility of the 10 product -- the material for use in the product. 11 They also test the materials once they're 12 actually assembled into the final configuration of a 13 product, too, because you're concerned also about the		*[Counter Designation to BSC 328:23-330:5]* *ai073113, (Page 125:21 to 125:24)* *125* *21 Q Okay. I'm going to hand you what I've marked* *22 as Exhibit 465.* *23 (Exhibit Number 465* *24 marked for identification)* *ai073113, (Page 127:5 to 127:15)* *127* *5 Boston* *6 Scientific has used the synthetic material as a vascular* *7 graft and in other nonvascular reconstructive* *8 applications, and urethral*

14 interaction of various materials in a configuration, and 15 the processes that are used to put those various 16 materials together can also modify materials. For 17 instance, if you weld them or heat them or things of 18 that nature, it can change the characteristic of the 19 material. 20 So they have specific biocompatibility tests, 21 batteries of tests that they put them through. Every 22 single material at Boston Scientific is handled that 23 way. 24 Q And would those tests be done at the 330 1 development stage? 2 A They could be done as early -- if things are 3 well-defined, they could be done as early as late 4 definition phase, but primarily they're done in the 5 development phase. *** 6 Q And then the next step is validation and scale- 7 up. Tell the jury what that means. 8 A So once the product design is frozen and the 9 product has been verified as meeting its initial product 10 specification -- in other words, it works well, the 11 performance of the product is such that it's as 12 specified and predicted, the product meets those 13 specification requirements -- the decision is made to 14 move into process development work, so all of the 15 equipment associated with manufacturing the product and 16 manufacturing it in such a way that it's extremely 17 repeatable. 18 The process validation work is something that 19 is handled by the manufacturing and engineering team as 20 part of the manufacturing group. And in parallel with 21 that you're preparing for design validation. Design 22 validation is conducted to determine does the product 23 meet the initial user requirements or the physician 24 requirements, the physician needs. 331		*sling procedures have been* *9 practiced for more than 20 years. Prior to its release* *10 the product met all of the standard engineering and* *11 biocompatibility testing commonly applied to implants* *12 and it satisfied all US and European regulatory* *13 requirements."* *14 Did I read that right that time?* *15 A Yes, you did.* *ai073113, (Page 128:4 to 128:10)* *128* *4 Q Okay. Now, go back to the first page where it* *5 says "key points." Would you read me the fourth bullet* *6 point.* *7 A "In conjunction with any future sling* *8 materials, Boston Scientific will gather clinical data* *9 to assess product performance in a broad spectrum of* *10 clinical situations."* *ai073113, (Page 133:13 to 133:17)* *133* *13 Q Okay. So with regard to future sling* *14 materials, with regard to the product Marlex, Boston* *15 Scientific here is saying we will gather clinical data* *16 to assess product performance. Correct?* *17 A Correct.* *ai073113, (Page 134:4 to 134:8)* *134* *4 Q Before the pelvic organ prolapse products were* *5 released on the market by Boston Scientific, were any*

And product that's produced on the manufacturing process that's validated, samples are taken from that, and those products are then presented to physicians typically in the form of a test that simulates the final use environment, simulates the operating room for instance in this case. And it's conducted by physician customers to determine does the product work as it's specified that it should. Once that design validation is done and it's understood that the product meets its design requirements, manufacturing is scaled up to a high level. This is the point at which the product would have been submitted to various regulatory agencies, whether it's the FDA or Japan PMDA, other global regulatory bodies. And then once the product has passed its final process validation, design validation activity, it moves into a commercialization phase where ultimately it's brought to market. *** 333 Q And then you mentioned clinical. What would clinical's role be in the project team? A Clinical is determining, you know, what is necessary in terms of potential clinical testing and when clinical testing should occur with that new product or that product modification. Most of the time in the division, urology women's health, because the product was a -- what's referred to as a simple 510(k) regulatory pathway, that doesn't require clinicals until -- it doesn't require clinicals to be approved by the agency. Clinical trials are done after launch, but in some instances where there's a different regulatory pathway known as a PMA there are clinical trials conducted on the products before they come to market.	331:13-16 FRE 401, 402, 403 FDA Reference 333:7-15 FRE 401, 402,403 FDA Reference	*studies -- clinical studies completed involving Marlex?* *MR. ANIELAK: I object to the form.* *A Not that I'm aware of.*

*** 4 Q Why -- The process, the five-step process, why 5 is that process used at Boston Scientific? Why use that 6 process? What's the purpose? 7 A It's a process that's used not only in medical 8 device development. It's a process that's used in 9 development of many new products across multiple 10 industries. 11 The reason it's done is it's a tried and true 12 process. It's very successful. It's a way to challenge 13 the engineering teams, challenge the assumptions, to be 14 assured that the work that's being done is appropriate 15 and meets specification. 16 Within Boston Scientific, there are key 17 elements in the medical device design and development 18 that are unique, of course. It's critical that the 19 design history file work meet what's referred to by the 20 FDA as design controls. 21 And the FDA puts design control guidance 22 procedures in place that medical-device companies follow 23 in such a way to be assured that the right 24 considerations for physician and patient are kept in 336 1 mind as the product is being developed.	335:16-336:1 FRE 401, 402, 403 FDA Reference	

1. **Counter Exhibits**
   a. Intoccia 465 (with FDA references redacted)

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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